



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

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MEMORANDUM

Date: January 13, 2008

**SUBJECT:** EFED Response to Acetochlor Registration Partnership Submitted Waiver  
Request for Acetochlor Mallard Avian Reproduction Study 71-4b

**TO:** Vickie Walters, PM Team Reviewer  
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Registration Division (S7337)

**FROM:** N.E. Federoff, Wildlife Biologist  
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**THROUGH:** Mah T. Shamim, Ph.D., Branch Chief  
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The following is the Environmental Fate and Effects Division's (EFED) response to Monsanto regarding a waiver request (MRID 475074-01) for a Mallard duck (*Anus platyrhynchos*) avian reproduction study (71-4b) with the herbicide Acetochlor. Monsanto believes another study would result in unnecessary duplication of data as well as unnecessary use of experimental animals. Five avian reproduction studies have previously been submitted. They request that EFED change the classification of the previously submitted study (MRID 443831-01) from supplemental to core.

Acetochlor is a selective non-systemic herbicide classified as an acid anilide or more specifically as a chloroacetamide. The mode of action is adsorption through the coleoptile of germinating seedlings and secondarily through the root system. Acetochlor controls weeds by interfering with normal germination and seedling development. Acetochlor does not control established or



germinated weeds present at the time of application (Acetochlor EC labeling). Acetochlor is used to control annual grasses and certain broadleaf weeds.

Data suggest that acetochlor is slightly toxic to practically non-toxic to birds from acute exposure. In the most current assessment, EFED based avian acetochlor chronic toxicity risk on reductions in the number 14-day-old survivors, the number of live 3-week embryos and normal hatchlings from the currently debated mallard duck 2-generation reproductive study (LOAEC of 150 ppm and NOAEC of 30 ppm). EFED originally deemed the study in question as supplemental because of deviations in guidelines. EFED requested that the study be repeated.

The most significant guideline deviations were that the temperature of the rooms housing the birds was too low (guideline is 21C and test was 15-17C), humidity was too high (guideline is 55% and test was 70-71%) and that an increase in photoperiod to stimulate reproduction took place 2 weeks earlier than the guidelines recommend (on week 7 instead of on week 9).

EFED agrees that a new study does not need to be submitted. Even with the deviations listed, a statistically valid NOAEC of 30 ppm was calculated. In addition, since there indeed were guideline deviations in the study, the classification should remain supplemental. Studies deemed with the supplemental classification can still be used for the purposes of risk assessment.